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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,947	09/09/2003	Sean C. Semple	PAT-2600-CNT2	3517

500 7590 05/02/2007  
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
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SEATTLE, WA 98104

EXAMINER
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NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/658,947

**Applicant(s)**

SEMPLE ET AL.

**Examiner**

David M. Naff

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 85-91, 93-102 and 104-110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 85-91, 93-102 and 105-110 is/are allowed.
- 6) ☒ Claim(s) 104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for  
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/8/07 has been entered.

An amendment of 1/23/07 filed after final rejection has been  
10 entered. The amendment canceled claim 103.

Claims examined on the merits are 85-91, 93-102 and 104-110, which are all claims in the application.

***Claim Rejections - 35 USC § 112***

Claim 104 is rejected under 35 U.S.C. 112, first paragraph, as  
15 failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 Support is not found in the specification for the nucleic acid of the claimed nucleic acid-lipid particle not being substantially degraded after incubation of the particle in serum at 37° C for 30 minutes as required by claim 104.

### ***Response to Arguments***

The remarks in the amendment urge that support is provided by Example 10 in the specification (page 7) disclosing that free phosphorothioate oligodeoxynucleotide shows significant breakdown in serum within 30 minutes, and that encapsulated phosphorothioate oligodeoxynucleotide in serum is not degraded after 24 hours. However, in Example 10, the nucleic acid is phosphorothioate oligodeoxynucleotide. Claim 104 encompasses any nucleic acid. It cannot be assumed that any free nucleic acid will degrade in serum in the same time as free phosphorothioate oligodeoxynucleotide. Some nucleic acids may degrade in less time than 30 minutes and other nucleic acids may degrade in a longer time than 30 minutes. The time of not degrading in 30 minutes in the present claim is based on free phosphorothioate oligodeoxynucleotide degrading in 30 minutes. However, when the nucleic acid is not phosphorothioate oligodeoxynucleotide, the time for the free nucleic acid degrading will not necessarily be 30 minutes, and can be less or more than 30 minutes. Therefore, the time for the encapsulated nucleic acid not degrading will be less or more than 30 minutes when the time is based on the time for the free nucleic acid degrading.

### ***Conclusion***

Claim 104 is free of the prior art.

Claims 85-91, 93-102 and 105-110 are allowable.

Any inquiry concerning this communication or earlier

communications from the examiner should be directed to David M. Naff


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whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925.

5 The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained  
10 from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-  
15 9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
David M. Naff  
Primary Examiner  
Art Unit 1657

20 DMN  
4/27/07